



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/053,750

01/21/2002

Morton M. Mower

2206-001 C

6121

22208

7590

05/20/2008

ROBERTS, MARDULA & WERTHEIM, LLC
11800 SUNRISE VALLEY DRIVE
SUITE 1000
RESTON, VA 20191

EXAMINER

GETZOW, SCOTT M

ART UNIT

PAPER NUMBER

3762

MAIL DATE

DELIVERY MODE

05/20/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/053,750	Applicant(s) MOWER, MORTON M.	
	Examiner /Scott M. Getzow/	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-15, 17-20, 22, 24, 25, 34-36, 38, 47, 50 and 58-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-15, 17-20, 22, 24, 25, 34-36, 38, 47, 50, 58-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 102

1. Claims 12-14,17,18,19/17,22,24,25,34,35,59 are rejected under 35 U.S.C. 102(b) as being anticipated by Freeman (5,205,284).

Freeman is considered to anticipate all of the subject matter of the above claims. Figure 1 of Freeman shows means for creating an electric potential between two points in the vicinity of a muscle (70, 72). It can also be fairly interpreted that the term 'vicinity' could encompass the heart muscle since that term is very broad. Figure 1 also shows circuitry which can produce subthreshold anodal stimulation, see also figure 6b where subthreshold pacing pulses 100 are shown. Also, the pacing pulses can be controlled as to when they start, and their duration and magnitude, by the circuitry of figure 1, see also col. 5. In the above apparatus claims, the phrase 'for varying conduction velocity' in the preamble is considered to be intended use which can be accomplished by the

structure of Freeman. Re the above method claims, it is considered to be inherent in the use of Freeman that the conduction velocity is varied. That is, during the normal operation of the Freeman device, the patient's conduction velocity in a muscle is inherently modified. Further, cardiac feedback signals shown in figure 1 of Freeman are considered to emanate from a sensor. Still further, modification of the patient's cardiac output is considered to be inherently performed by the device of Freeman since the act of pacing the heart would modify the output. Re claims 12-14,18, the background pulses of Freeman can be biphasic, and are non-excitatory. Further, the amplitude of the background pulses can be adjusted, depending on the patient's reaction to the stimulus, so that they could be considered to be in the range of typical 'pacing' pulses.

2. Claims 15,17,19/17,24,25,34,35,36,38,47,50,61-63 are rejected under 35 U.S.C. 102(b) as being anticipated by Scherlag (5,320,642).

Scherlag teaches an implantable pacemaker which can deliver to the patient's heart a subthreshold DC signal which is below the level required to excite the tissue of the heart, see col. 2. Col.4:1+ teaches that the output signal can be adjusted, which is interpreted as meaning that the start time, magnitude, duration, of the signals can be modified by the device. Further, column 2 also teaches that the stimulation can be a train of pulses. As mentioned supra regarding the Freeman device, the device of Scherlag is considered to inherently alter the conduction velocity and/or contractility of the patient's heart during normal operation of the device. Still further, the lead used in Scherlag can be bipolar or tripolar and the stimulus generator, as is known in the art, could switch from

Application/Control Number:
10/053,750
Art Unit: 3762

Page 5

one electrode to another to change the polarity of the stimulation depending on user preferences.

Claim Rejections - 35 USC § 103

3. Claims 61-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scherlag (5,320,642).

Re claims 61-63, it would have been obvious to also have a pacing feature with the device of Scherlag since such a device can be used in a pacemaker and that patient's with heart block also may need pacing.

4. Claims 58-60, 64-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scherlag (5,320,642) in view of Nichols et al (5,374,282).

Nichols teaches the use of a pressure sensor and a oxygen sensor. Such sensors are common in the art to help determine the state of the heart and to help in providing therapy.

Application/Control Number:
10/053,750
Art Unit: 3762

Page 6

Claim Rejections - 35 USC § 112

5. Claims 22,38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claims 22 and 38, 'DC electric current' lacks proper antecedent basis.

Since new rejections have been made, this action is not made final.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to /Scott M. Getzow/ whose telephone number is

Application/Control Number:
10/053,750
Art Unit: 3762

Page 7

(571) 272-4946. The examiner can normally be reached
on M-F, 9-5.

If attempts to reach the examiner by telephone are
unsuccessful, the examiner's supervisor, Angela Sykes
can be reached on (571) 272-4955. The fax phone number
for the organization where this application or
proceeding is assigned is 571-273-8300.

Application/Control Number:
10/053,750
Art Unit: 3762

Page 8

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Scott M. Getzow/
Primary Examiner
Art Unit 3762

SMG

Application/Control Number:
10/053,750
Art Unit: 3762

Page 9